PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: MICHAEL VERGA
CONNOLLY BOVE LODGE & HUTZ LLP
1875 EYE STREET, NW
SUITE 1100
WASHINGTON, DC 20006

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing (*day/month/year*) 05 JUN 2009

Applicant's or agent's file reference 22409-00501-WO		**FOR FURTHER ACTION** See paragraph 2 below
International application No. PCT/US2009/038932	International filing date (*day/month/year*) 31 March 2009	Priority date (*day/month/year*) 31 March 2008
International Patent Classification (IPC) or both national classification and IPC IPC(8) - A61F 2/18 (2009.01) USPC - 600/25		
Applicant COCHLEAR AMERICAS		

1. This opinion contains indications relating to the following items:

- [x] Box No. I Basis of the opinion
- [ ] Box No. II Priority
- [ ] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [ ] Box No. IV Lack of unity of invention
- [x] Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI Certain documents cited
- [ ] Box No. VII Certain defects in the international application
- [ ] Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Date of completion of this opinion 22 May 2009	Authorized officer: Blaine Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

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Box No. I **Basis of this opinion**

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into ____________ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:

   a. type of material

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material

   ☐ on paper

   ☐ in electronic form

   c. time of filing/furnishing

   ☐ contained in the international application as filed

   ☐ filed together with the international application in electronic form

   ☐ furnished subsequently to this Authority for the purposes of search

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

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Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	4, 5, 8, 9, 11-14, 20, 21, 24, 25 27-30, 34, 35, 37, 38, 40	YES
	Claims	1-3, 6, 7, 10, 15-19, 22, 23, 26, 31-33, 36, 39	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-40	NO
Industrial applicability (IA)	Claims	1-40	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-3, 6, 7, 10, 15-19, 22, 23, 26, 31-33, 36, and 39 lack novelty under PCT Article 33(2) as being anticipated by Leysieffer. Referring to claim 1, Leysieffer, discloses a system for fitting a hearing prosthesis to a recipient, comprising: a stimulation arrangement configured to at least one of mechanically and acoustically stimulate the recipient's inner ear based on an input signal (Paras. [0042] and [0044]); a neural response detection arrangement configured to detect the recipient's neural responses to the stimulation (Paras. [0042] and [0044]); and a processor configured to assess the recipient's neural responses, and to adjust the operation of the hearing prosthesis based on the assessment of the neural responses (Para. [0042]).

Referring to claim 2, Leysieffer, discloses the system of claim 1, wherein the input signal has a frequency spectrum comprising a broad range of audible frequencies (Para. [0109]).

Referring to claim 3, Leysieffer, discloses the system of claim 1, wherein the stimulation arrangement comprises: an audio output device configured to generate an amplified audio signal representing the input signal (audiometer, Para. [0021]).

Referring to claim 6, Leysieffer discloses the system of claim 1, wherein the stimulation arrangement comprises: an actuator (transducer, Para. [0114]) configured to receive electrical signals representing the input signal and configured to vibrate in response to the electrical signals, wherein the actuator is coupled to the recipient's ossicular chain, and wherein the ossicular chain delivers the vibration to the recipient's inner ear (Para. [0114]).

Referring to claim 7, Leysieffer discloses the system 0 f claim 1, further comprising a signal generator to generate the input signal (audiometer, Para. [0021]).

Referring to claim 10, Leysieffer discloses the system of claim 1, wherein the processor is configured to implement, in real-time, a set of algorithms which assess the neural responses, and adjust the hearing prosthesis operations (Paras. [0042] and [0044]).

Referring to claims 15, Leysieffer discloses the system of claim 1, wherein the system is configured to be integrated into the hearing prosthesis (coupling rod 55, Fig. 10).

Referring to claim 16, Leysieffer discloses the system of claim 15, configured to periodically fit the hearing prosthesis (coupling rod 55) to the recipient during operation of the prosthesis (Para. [0111]; "and has a surface composition and surface size such that, by placing the coupling end against the coupling site, dynamic tension-compression force coupling of the coupling element and ossicular chain occur due to surface adhesion which is sufficient for secure mutual connection of the coupling element and the ossicular chain.).

Referring to claim 17, Leysieffer discloses a hearing prosthesis, comprising: a stimulation arrangement configured to at least one of mechanically and acoustically stimulate the recipient's inner ear based on an input signal (Paras. [0042] and [0044]); a neural response detection arrangement configured to detect the recipient's neural responses to the stimulation (Paras. [0042] and [0044]); and a processor configured to assess the recipient's neural responses (Para. [0042]), and to adjust the operation of the hearing prosthesis based on the assessment of the neural responses (Para. [0042]).

Referring to claim 18, Leysieffer discloses the prosthesis of claim 17, wherein the input signal has a frequency spectrum comprising a broad range of audible frequencies (Para. [0109]).

Referring to claim 19, Leysieffer discloses the prosthesis of claim 17, wherein the stimulation arrangement comprises: an audio output device configured to generate an amplified audio signal representing the input signal (audiometer, Para. [0021]).

Referring to claim 22, Leysieffer discloses the prosthesis of claim 17, wherein the stimulation arrangement comprises: an actuator (transducer, Paras. [0114] and [0036]) configured to receive electrical signals representing the input signal and configured to vibrate in response to the electrical signals, wherein the actuator is coupled to the recipient's ossicular chain, and wherein the ossicular chain delivers the vibration to the recipient's inner ear (Para. [0114]).

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Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:

Referring to claim 23, Leysieffer discloses the prosthesis of claim 17, further comprising a signal generator to generate the input signal (audiometer, Para. [0021]).

Referring to claim 26, Leysieffer discloses the prosthesis of claim 17, wherein the processor is configured to implement, in real time, a set of algorithms which assess the neural responses, and adjust the hearing prosthesis operations (Paras. [0042] and [0044]).

Referring to claim 31, Leysieffer discloses a method for fitting a hearing prosthesis to a recipient, comprising: at least one of mechanically and acoustically stimulating the recipient's inner ear (Para. [0044]); detecting the recipient's neural responses to the stimulation (Para. [0044]); assessing the recipient's neural responses (Para. [0042]); and adjusting the operation of the hearing prosthesis based on the assessment of the neural responses (Para. [0042]).

Referring to claim 32, Leysieffer discloses the method of claim 31, further comprising: generating a signal having a frequency spectrum comprising a broad range of audible frequencies (Para. [0109]); and stimulating the recipient's inner ear based on the generated signal (Para. [0109]).

Referring to claim 33, Leysieffer discloses the method of claim 31, wherein stimulating the recipient comprises: acoustically stimulating the recipient with an audio output device configured to generate an amplified audio signal representing an input signal (audiometer, Para. [0021]).

Referring to claim 36, Leysieffer discloses the method of claim 31, wherein stimulating the recipient comprises: mechanically stimulating the recipient's inner ear with a stimulation arrangement (Paras. [0042] and [0044]) comprising: an actuator (transducer, Paras. [0114] and [0036]) configured to receive electrical signals representing the input signal and configured to vibrate in response to the electrical signals, wherein the actuator is coupled to the recipient's ossicular chain, and wherein the ossicular chain delivers the vibration to the recipient's inner ear (Para. [0114]).

Referring to claim 39, Leysieffer discloses the method of claim 31, further comprising: implementing, in real time, a set of algorithms which assess the neural responses, and adjust the hearing prosthesis operations (Paras. [0042] and [0044]).

Claims 4, 5, 20, 21, 24, 25, 34, and 35 lack an inventive step under PCT Article 33(3) as being obvious over Leysieffer, in view of Leysieffer et al.
Referring to claim 4, Leysieffer discloses the system of claim 1, wherein the stimulation arrangement comprises: an actuator (transducer, Paras. [0114] and [0036]) configured to receive electrical signals representing the input signal and configured to vibrate in response to the electrical signals, and a coupler (coupling rod, [0036]) connecting the actuator to the stapes such that vibration of the actuator results in waves of fluid motion in a recipient's semicircular canal (tympanic canal, Para. [0013]). However, Leysieffer does not teach a stapes prosthesis having a first end configured to be positioned abutting an opening in the semicircular canal. However, Leysieffer et al. discloses a stapes prosthesis (stirrup prosthesis 28) having a first end configured to be positioned abutting an opening in a (oval window 22, Col. 9, Lns. 7-31, Fig. 5). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Leysieffer's system to include a stapes prosthesis having a first end configured to be positioned abutting an opening in the semicircular canal, as taught by Leysieffer et al, to reduce acoustic feedback.

Referring to claim 5, Leysieffer discloses the system 0 f claim 1, wherein the stimulation arrangement comprises: an actuator configured to receive electrical signals representing the input signal and configured to vibrate in response to the electrical signals (transducer, Para. [0114]); an elongate rod extending longitudinally from the actuator (transducer, Paras. [0114] and [0036]) connecting the actuator to the stapes such that vibration of the actuator results in waves of fluid motion in a recipient's scala tympani (Paras. [0012] and [0013], "its active transducer element is located itself in the middle ear region in the tympanic cavity"). However, Leysieffer does not teach a stapes prosthesis having first and second ends, the first end having a surface configured to be positioned abutting the round window in the recipient's cochlea, and wherein the first end surface is substantially orthogonal to a longitudinal axis extending through the actuator. Yet, Leysieffer et al. discloses a stapes prosthesis (stirrup prosthesis 28) having first and second ends (the bottom and top ends of stirrup prosthesis 28, as shown in Fig. 5), the first end (the bottom end of stirrup 28, Fig. 5) having a surface configured to be positioned abutting the round window (oval window 22) in the recipient's cochlea, and wherein the first end surface is substantially orthogonal to a longitudinal axis extending through the actuator (Col. 9, Lns. 7-31, Fig. 5). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Leysieffer's system to include a stapes prosthesis having first and second ends, the first end having a surface configured to be positioned abutting the round window in the recipient's cochlea, and wherein the first end surface is substantially orthogonal to a longitudinal axis extending through the actuator, as taught by Leysieffer et al., in order to reduce acoustic feedback and provide adequate sound quality.

Referring to claim 20, Leysieffer discloses the system of claim 17, wherein the stimulation arrangement comprises: an actuator (transducer, Paras. [0114] and [0036]) configured to receive electrical signals representing the input signal and configured to vibrate in response to the electrical signals, and a coupler (coupling rod, [0036]) connecting the actuator to the stapes such that vibration of the actuator results in waves of fluid motion in a recipient's semicircular canal (tympanic canal, Para. [0013]). However, Leysieffer does not teach a stapes prosthesis having a first end configured to be positioned abutting an opening in the semicircular canal. Yet, Leysieffer et al. discloses a stapes prosthesis (stirrup prosthesis 28) having a first end configured to be positioned abutting an opening in a (oval window 22, Col. 9, Lns. 7-31, Fig. 5). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Leysieffer's system to include a stapes prosthesis having a first end configured to be positioned abutting an opening in the semicircular canal, as taught by Leysieffer et al, to reduce acoustic feedback.

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Referring to claim 21, Leysieffer discloses the prosthesis of claim 17, wherein the stimulation arrangement comprises: an actuator configured to receive electrical signals representing the input signal and configured to vibrate in response to the electrical signals (transducer, Para. [0114]); an elongate rod extending longitudinally from the actuator connecting the actuator (transducer, Paras. [0114] and [0036]) to the stapes prosthesis such that vibration of the actuator results in waves of fluid motion in a recipient's scala tympani (Paras. [0012] and [0013], "its active transducer element is located itself in the middle ear region in the tympanic cavity"). However, Leysieffer does not teach a stapes prosthesis having first and second ends, the first end having a surface configured to be positioned abutting the round window in the recipient's cochlea, and wherein the first end surface is substantially orthogonal to a longitudinal axis extending through the actuator. Yet, Leysieffer et al. discloses a stapes prosthesis (stirrup prosthesis 28) having first and second ends (the bottom and top ends of stirrup prosthesis 28, as shown in Fig. 5), the first end (the bottom end of stirrup 28, Fig. 5) having a surface configured to be positioned abutting the round window (oval window 22) in the recipient's cochlea, and wherein the first end surface is substantially orthogonal to a longitudinal axis extending through the actuator (Col. 9, Lns. 7-31, Fig.5). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Leysieffer's system to include a stapes prosthesis having first and second ends, the first end having a surface configured to be positioned abutting the round window in the recipient's cochlea, and wherein the first end surface is substantially orthogonal to a longitudinal axis extending through the actuator, as taught by Leysieffer et al., in order to reduce acoustic feedback and provide adequate sound quality.

Referring to claims 24 and 25, Leysieffer discloses the prosthesis of claim 17. However, Leysieffer does not teach [Claim 24] the detection arrangement comprises: first and second electrical contacts disposed on the recipient's inner ear to detect the recipient's neural responses to the stimulation; and [Claim 25] the prosthesis of claim 24, further comprising: a sense amplifier configured to receive signals from the first and second contacts. Yet, Leysieffer et al., teaches a cochlear implant [Claim 24] wherein the detection arrangement (receiver/stimulator 22, Para. [0090]) comprises: first and second electrical contacts (stim 1 or stim 2, Paras. [0090] and [0101]) disposed on the recipient's inner ear to detect the recipient's neural responses to the stimulation; and [Claim 25] the system of claim 8, further comprising: a sense amplifier (receiver/stimulator 22, Paras. [0090] and [0101]) configured to receive signals from the first and second contacts (stim 1 or stim 2). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Leysieffer's system to include first and second electrical contacts disposed on the recipient's inner ear to detect the recipient's neural responses to the stimulation; and a sense amplifier configured to receive signals from the first and second contacts, as taught by Leysieffer et al., in order to prevent damage to the inner ear.

Referring to claim 34, Leysieffer discloses the method of claim 31, wherein stimulating the recipient comprises: directly mechanically stimulating the recipient's inner ear with a stimulation arrangement (Paras. [0042] and [0044]) comprising: an actuator configured to receive electrical signals representing the input signal and configured to vibrate in response to the electrical signals (transducer, Para. [0114]), and a coupler (coupling rod, [0036]) connecting the actuator to the stapes such that vibration of the actuator results in waves of fluid motion in a recipient's semicircular canal (tympanic canal, Para. [0013]). However, Leysieffer does not teach a stapes prosthesis having a first end configured to be positioned abutting an opening in the semicircular canal. Yet, Leysieffer et al. discloses a stapes prosthesis (stirrup prosthesis 28) having a first end configured to be positioned abutting an opening in a (oval window 22, Col. 9, Lns. 7-31, Fig. 5). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Leysieffer's system to include a stapes prosthesis having a first end configured to be positioned abutting an opening in the semicircular canal, as taught by Leysieffer et al, to reduce acoustic feedback.

Referring to claim 35, Leysieffer discloses the method of claim 31, wherein stimulating the recipient comprises: directly mechanically stimulating the recipient's inner ear with a stimulation arrangement (Paras. [0042] and [0044]) comprising: an actuator (transducer, Paras. [0114] and [0036]) configured to receive electrical signals representing the input signal and configured to vibrate in response to the electrical signals; and an elongate rod (coupling rod, Para. [0036]) extending longitudinally from the actuator connecting the actuator to the stapes such that vibration of the actuator results in waves of fluid motion in a recipient's scala tympani (tympanic canal, Para. [0013]). However, Leysieffer does not teach a stapes prosthesis having first and second ends, the first end having a surface configured to be positioned abutting the round window in the recipient's cochlea, and wherein the first end surface is substantially orthogonal to a longitudinal axis extending through the actuator. Yet, Leysieffer et al. discloses a stapes prosthesis (stirrup prosthesis 28) having first and second ends (the bottom and right top ends of stirrup prosthesis 28, as shown in Fig. 5), the first end (the bottom end of stirrup 28, Fig. 5) having a surface configured to be positioned abutting the round window (oval window 22) in the recipient's cochlea, and wherein the first end surface is substantially orthogonal to a longitudinal axis extending through the actuator (Col. 9, Lns. 7-31, Fig.5). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Leysieffer's system to include a stapes prosthesis having first and second ends, the first end having a surface configured to be positioned abutting the round window in the recipient's cochlea, and wherein the first end surface is substantially orthogonal to a longitudinal axis extending through the actuator, as taught by Leysieffer et al., in order to reduce acoustic feedback and provide adequate sound quality.

Claims 8, 9, 11, 27, 37, 38, and 40 lack an inventive step under PCT Article 33(3) as being obvious over Leysieffer, in view of Ibrahim et al. (hereinafter referred to as Ibrahim).
Referring to claims 8 and 9, Leysieffer discloses the system of claim 1. However, Leysieffer does not teach [Claim 8] wherein the detection arrangement comprises: first and second electrical contacts disposed on the recipient's inner ear to detect the recipient's neural responses to the stimulation; and [Claim 9] the system of claim 8, further comprising: a sense amplifier configured to receive signals from the first and second contacts. Yet, Ibrahim teaches a cochlear implant [Claim 8] wherein the detection (receiver/stimulator 22, Para. [0090]) arrangement comprises: first and second electrical contacts (stim 1 or stim 2, Paras. [0090] and [0101]) disposed on the recipient's inner ear to detect the recipient's neural responses to the stimulation; and [Claim 9] the system of claim 8, further comprising: a sense amplifier (receiver/stimulator 22, Paras. [0090] and [0101]) configured to receive signals from the first and second contacts (stim 1 or stim 2). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Leysieffer's system to include a first and second electrical contacts disposed on the recipient's inner ear to detect the recipient's neural responses to the stimulation; and a sense amplifier configured to receive signals from the first and second contacts, as taught by Ibrahim, in order to prevent damage to the inner ear.

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Referring to claim 11, Leysieffer discloses the system of claim 1. However, Leysieffer does not teach the processor is configured to assess the neural responses by comparing the responses to target neural responses. Yet, Ibrahim teaches a cochlear implant wherein the processor (circuitry 10, Fig. 2) is configured to assess the neural responses by comparing the responses to target neural responses (Para. [0101]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Leysieffer's system to include a processor is configured to assess the neural responses by comparing the responses to target neural responses, as taught by Ibrahim, to automatically adjust the implant.

Referring to claim 27, Leysieffer discloses the prosthesis of claim 17. However, Leysieffer does not teach the processor is configured to assess the neural responses by comparing the responses to target neural responses. Yet, Ibrahim teaches a cochlear implant wherein the processor (circuitry 10, Fig. 2) is configured to assess the neural responses by comparing the responses to target neural responses (Para. [0101]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Leysieffer's system to include a processor is configured to assess the neural responses by comparing the responses to target neural responses, as taught by Ibrahim, to automatically adjust the implant.

Referring to claims 37 and 38, Leysieffer discloses the method of claim 31. However, Leysieffer does not teach wherein [Claim 37] detecting the recipient's neural responses to the stimulation comprises: detecting the neural responses with first and second electrical contacts disposed on the recipient's inner ear; and [Claim 38] the method of claim 37, further comprising: delivering signals representing the detected neural responses to a sense amplifier. Yet, Ibrahim teaches a method [Claim 37] wherein detecting the recipient's neural responses to stimulation comprises: detecting neural responses using first and second electrical contacts (stim 1 or stim 2, Paras. [0090] and [0101]) disposed on the recipient's inner ear; and [Claim 38] the method of claim 37, further comprising: delivering signals representing the detected neural responses to a sense amplifier (receiver/stimulator 22, Paras. [0090] and [0101]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Leysieffer's system to include provide the arrangement above, as taught by Ibrahim, in order to detect and prevent damage to the inner ear.

Referring to claim 40, Leysieffer discloses the method of claim 31. However, Leysieffer does not teach assessing the neural responses comprises: comparing the detected responses to target neural responses. Yet, Ibrahim teaches assessing the neural responses by comparing the responses to target neural responses (Para. [0101]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Leysieffer's system to include a assessing the neural responses by comparing the responses to target neural responses, as taught by Ibrahim, to automatically adjust the implant.

Claims 12-14, and 28-30 lack an inventive step under PCT Article 33(3) as being obvious over Leysieffer, in view of Bachler.
Referring to claims 12 – 14, Leysieffer discloses the system of claim 1. However, Leysieffer does not teach [Claim 12] the processor is configured to adjust the operation of the hearing prosthesis to provide at least one of equal loudness and optimal loudness restoration across a desired audible frequency range; [Claim 13] the processor is configured to adjust the operation of the hearing prosthesis to improve speech perception by the recipient; and [Claim 14] the processor is configured implement one or more safety guidelines which prevent adjustment of the hearing prosthesis that would result in stimulation damaging to the recipient's hearing. Yet, Bachler teaches a loudness limiter that includes [Claim 12] a processor (processing unit 3) that is configured to adjust the operation of the hearing prosthesis to provide at least one of equal loudness and optimal loudness restoration across a desired audible frequency range (Col. 3, Lns. 30-33); [Claim 13] the processor (processing unit 3) is configured to adjust the operation of the hearing prosthesis to improve speech perception by the recipient (Col. 3, Lns. 30-33; The user will automatically adjust his speech according to what he hears.); and [Claim 14] the processor (processing unit 3) is configured implement one or more safety guidelines which prevent adjustment of the hearing prosthesis that would result in stimulation damaging to the recipient's hearing (Col. 3, Lns. 35-41). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Leysieffer's system to include the arrangement above, as taught by Bachler, to prevent damage to the user's ears.

Referring to claims 28-30, Leysieffer discloses the prosthesis of claim 17. However, Leysieffer does not teach [Claim 28] the processor is configured to adjust the operation of the hearing prosthesis to provide at least one of equal loudness and optimal loudness restoration across a desired audible frequency range; [Claim 29] the processor is configured to adjust the operation of the hearing prosthesis to improve speech perception by the recipient; and [Claim 30] wherein the processor is configured implement one or more safety guidelines which prevent adjustment of the hearing prosthesis that would result in stimulation damaging to the recipient's hearing. Yet, Bachler teaches a loudness limiter that includes [Claim 28] a processor (processing unit 3) that is configured to adjust the operation of the hearing prosthesis to provide at least one of equal loudness and optimal loudness restoration across a desired audible frequency range (Col. 3, Lns. 30-33); [Claim 29] the processor (processing unit 3) is configured to adjust the operation of the hearing prosthesis to improve speech perception by the recipient (Col. 3, Lns. 30-33; The user will automatically adjust his speech according to what he hears.); and [Claim 30] the processor (processing unit 3) is configured implement one or more safety guidelines which prevent adjustment of the hearing prosthesis that would result in stimulation damaging to the recipient's hearing (Col. 3, Lns. 35-41). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Leysieffer's system to include the arrangement above, as taught by Bachler, to prevent damage to the user's ears.

Claims 1-40 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.